EXHIBIT E

DECLARATION UNDER 35 U.S.C. §1.132

1103326-0502

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Cotton et al.
Serial No.	: 09/077,719
Filed	: June 8, 1998
For	: NOVEL FORM OF S-OMEPRAZOLE
Examiner	: J. Fan
Group Art Unit	: 1614

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents Washington, D.C. 20231.

John M. Genova — 32,224
Attorney Name — PTO Reg. No.

John M Genova — 4 May 2001
Signature — Date of Signature

Assistant Commissioner for Patents
Washington, D.C. 20231

Declaration of Frans W. Langkilde
(Under 37 C.F.R. §1.132)

Sir:

I, Frans W. Langkilde, Ph.D., declare as follows:

1. I am a citizen of Denmark. I graduated in 1987 from Aarhus University with a doctorate in Physical Chemistry.

2. AstraZeneca is the parent company of Astra Aktiebolag. The assignee of the referenced application is Astra Aktiebolag. I am presently employed by AstraZeneca and my current position is Group Leader, Analytical Development, Pharmaceutical and Analytical Research and Development. I have held this position since 2001. During the period 1999-2001, I was employed as Head of Section, Solid State Analysis, Preformulation and Biopharmaceutics. During the period 1993 to 1999, I was employed as a spectrometry specialist and then as a Group Leader, Solid State Analysis, Analytical Chemistry, by Astra Hässle AB, which is also part of the Astra Zeneca organization. My curriculum vitae is attached to this Declaration as Exhibit A.

3. I have read and understood the referenced patent application and I am familiar with the invention described and claimed therein. Specifically, the invention is directed to a new and advantageous form of the magnesium salt of S-omeprazole. As stated in the specification at page 3, line 3-9, the compound of the claimed invention is referred to as the magnesium salt of S-omeprazole trihydrate. The claimed magnesium salt of S-omeprazole trihydrate is substantially free from magnesium salts of R-omeprazole and other prior art forms of magnesium salts of S-omeprazole.

4. Set forth below is a summary of a side by side comparison, performed by Astra Hässle AB, of certain physical chemical properties of the claimed magnesium salt of S-omeprazole trihydrate and S-omeprazole magnesium dihydrate of the prior art.

5. Specifically, samples of the claimed magnesium salt of S-omeprazole trihydrate and the prior art compound, S-omeprazole magnesium dihydrate were prepared as confirmed to have the powder X-ray diffractogram as shown in Figures 1 and 4, respectively. These samples were then used as part of a comparative study with respect to the stability of each form. The details of that comparative study are reported below.

COMPARATIVE STUDY

Stability of the Claimed Trihydrate Form vs. the Prior Art Dihydrate Form

A. Preparation of Samples

Batches 1 and 3-5 (trihydrate) were synthesized to be the claimed magnesium salt of S-omeprazole, as confirmed with powder X-ray diffractometry (pXRD). (See Fig. 1).

Batch 2 was synthesized to be S-omeprazole magnesium salt dihydrate, as confirmed with pXRD. (See Fig. 4).

B. Stability

The chemical purity of each batch was determined by liquid chromatography and storage at 40°C, 75% relative humidity in open petri dishes in accordance with the ICH guidelines for accelerated stability testing. The results are as follows:

BATCH	0	1 MONTH	2 MONTHS	3 MONTHS	6 MONTHS	12 MONTHS
1 (trihydrate)	99.9	99.8	99.7	-	99.4	98.5
2 (dihydrate)	99.8	99.0	98.2	-	93.0	83.5
3 (trihydrate)	99.8	99.7	99.7	99.5	99.2	98.0
4. (trihydrate)	99.8	99.5	-	99.2	98.7	97.1
5. (trihydrate)	99.8	99.7	-	99.3	99.1	98.5

As can be seen in the Table, Batches 1 and 3-5 containing the claimed magnesium salt of S-omeprazole trihydrate showed a superior and unexpected improvement in stability, in comparison to the prior art dihydrate compound (Batch 2), after storage of six (6) months or longer.

C. Conclusion

The magnesium salt of S-omeprazole trihydrate is different when compared to the prior art S-omeprazole magnesium salt dihydrate. The solid state properties defining these forms are different. The claimed trihydrate is the more stable substance and, after storage of six (6) months or longer, is chemically more pure than the prior art dihydrate form. Furthermore, at the time the claimed invention was made, there was no suggestion that the magnesium salt of S-omeprazole existed in a trihydrate form. It was indeed surprising, therefore, to obtain the claimed compound and determine that the claimed magnesium salt of S-omeprazole trihydrate is more stable than the corresponding prior art compounds, thereby rendering the claimed trihydrate form more advantageous for use in pharmaceutical formulations.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: April 24, 2001

FW Langkilde

Frans W. Langkilde

CURRICULUM VITAE for FRANS W. LANGKILDE

Analytical Development 2, Pharmaceutical and Analytical Research and Development, AstraZeneca R&D Lund

Family name:	Langkilde
Given names:	Frans William
Date of birth:	June 3, 1952
Place of birth:	Bramstrup, Nr. Lyndelse, Denmark
Citizenship:	Danish
Education and academic degree:	BA, *Statskundskab* 1975. BSc, physics and chemistry 1980. MSc, physical and theoretical chemistry 1982. PhD, physical chemistry 1987.

Previous positions:

1981	Research associate, Chemistry Department, University of Utah, USA.
1983	Research associate, Chemistry Department, Risö National Laboratory, Denmark.
1987	National Science Foundation fellow.
1989	Assistant professor, Physical Chemistry, Royal Danish School of Pharmacy.
1992	Associate professor, Physical and Inorganic Chemistry, Danish Technical University.
1993	Spectrometry specialist and project leader, Analytical Chemistry, Astra Hässle AB.
1996	Group leader, Solid State Characterization, Analytical Chemistry, Astra Hässle AB.
1999	Group leader, Solid State Analysis, Preformulation and Biopharmaceutics, AstraZeneca R&D Mölndal.

Present position:

2001	Principal Scientist and Manager, Analytical Development 2, Pharmaceutical and Analytical Research and Development, AstraZeneca R&D Lund

Military degree: First lieutenant, Royal Danish Life Guards.

Publications: *ca* 47 publications on:
-Luminescence of aromatics at low temperature.
-Time-resolved and stationary, absorption and vibrational, spectroscopy of molecular excited states and free radicals; kinetics.
-Vibrational spectroscopy of pharmaceutical systems.

Conferences: Lectures or posters at numerous conferences.

Date: April 24., 2001

F.W. Langkilde

Frans W. Langkilde